

JMM:CPK
F. #2012R00759

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

-----X

UNITED STATES OF AMERICA

- against -

WILLIAM SCULLY,
also known as "Liam Scully,"

Defendant.

-----X

PROPOSED REQUESTS TO CHARGE

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Preliminary Statement

Pursuant to Rule 30 of the Federal Rules of Criminal Procedure, the government respectfully requests that the Court include the following instructions in its charge to the jury. In addition, the government requests leave to offer such other instructions as may become appropriate during the course of the trial.

The government respectfully requests that copies of the indictment and the jury instructions be provided to the jurors during their deliberations.

REQUEST NO. 1

General Requests

The government respectfully requests that the Court charge the jury in its usual manner on the following subjects:

- a) The Role of the Court and the Duties of the Jury;
- b) Equality of the Parties Before the Court;
- c) Jury Communications with Lawyers and the Court;
- d) Presumption of Innocence;
- e) Burden of Proof and Reasonable Doubt;
- f) Circumstantial Evidence and Direct Evidence;
- g) Function of the Superseding Indictment and What is Not Evidence;
- h) Permissible Inferences Drawn from the Evidence;
- i) Credibility of Witnesses and Discrepancies in Testimony;
- j) Deliberations;
- k) Right to See Exhibits and Have Testimony Read During Deliberations; and
- l) Verdict Must be Unanimous.

REQUEST NO. 2

Counts 20-36: Mail Fraud (18 U.S.C. § 1341):

The first specific counts I want to talk to you about are Counts Twenty through Thirty-Six of the indictment, which charge that the defendant devised a scheme to defraud and in furtherance of that scheme knowingly caused the mails to be used. Counts Twenty through Thirty-Six read in relevant part:

On or about the dates set forth below, within the Eastern District of New York and elsewhere, the defendant WILLIAM SCULLY, also known as 'Liam Scully,' together with others, did knowingly and intentionally devise a scheme and artifice to defraud customers of Pharmalogical, MDK and Taranis Medical Corp., and to obtain money and property from them, by means of materially false and fraudulent pretenses, representations and promises, and for the purpose of executing and attempting to execute such scheme and artifice, did place and cause to be placed in mail matters and things, to wit: packages of misbranded drugs to be delivered by private commercial interstate carriers for delivery, according to the instructions thereon, as set forth below

The relevant statute on this subject is section 1341 of Title 18 of the United States Code.

It provides:

Whoever, having devised or intending to devise any scheme or artifice to defraud, or for obtaining money or property by means of false or fraudulent pretenses, representations, or promises . . . for the purpose of executing such scheme or artifice or attempting so to do, places in any post office or authorized depository for mail matter, any matter or thing whatever to be sent or delivered by the Postal Service, or deposits or causes to be deposited any matter or thing whatever to be sent or delivered by any private or commercial interstate carrier . . . or knowingly causes to be delivered by mail or such carrier according to the direction thereon, or at the place at which it is directed to be delivered by the person to whom it is addressed, any such matter or thing, shall be [punished according to law].

In order to prove the defendant guilty of mail fraud, the government must prove each of the following elements beyond a reasonable doubt with respect to each count:

First, that there was a scheme or artifice to defraud or to obtain money or property by materially false and fraudulent pretenses, representations or promises, as alleged in the indictment;

Second, that the defendant knowingly and willfully participated in the scheme or artifice to defraud, with knowledge of its fraudulent nature and with specific intent to defraud or that he knowingly and intentionally aided and abetted others in the scheme; and

Third, that in execution of that scheme, the defendant used or caused the use of mails as specified in the indictment.

Authority: Sand, Modern Federal Jury Instructions, §§ 44-1, 44-3

REQUEST NO. 3

First Element of Mail Fraud: Scheme to Defraud

The first element that the government must prove beyond a reasonable doubt is that there was a scheme or artifice to defraud the customers of defendant or to obtain money or property by means of false or fraudulent pretenses, representations, or promises. This first element is almost self-explanatory.

A “scheme or artifice” is merely a plan for the accomplishment of an object. A scheme to defraud is any plan, device, or course of action to obtain money or property by means of false or fraudulent pretenses, representation, or promises reasonably calculated to deceive persons of average prudence.

“Fraud” is a general term which embraces all the various means which human ingenuity can devise and which are resorted to by an individual to gain an advantage over another by false representations, suggestions, suppression of the truth, or deliberate disregard for the truth.

Thus, a “scheme to defraud” is merely a plan to deprive another of money or property by trick, deceit, deception, or swindle.

The scheme to defraud is alleged to have been carried out by making false and misleading statements and representations.

A statement, representation, claim, or document is false if it is untrue when made and was then known to be untrue by the person making it or causing it to be made.

A representation or statement is fraudulent if it was falsely made with the intention to deceive.

Deceitful statements of half-truths or the concealment of material facts, and the expression of an opinion not honestly entertained may also constitute false or fraudulent statements under the statute.

The deception need not be premised upon spoken or written words alone. The arrangement of the words, or the circumstances in which they are used may convey the false and deceptive appearance. If there is deception, the manner in which it is accomplished is immaterial.

The failure to disclose information may also constitute a fraudulent representation if the defendant was under a legal, professional, or contractual duty to make such a disclosure, the defendant actually knew such disclosure was required to be made, and the defendant failed to make such disclosure with the intent to defraud.

The false or fraudulent representation *or* failure to disclose must relate to a material fact or matter. A material fact is one which would reasonably be expected to be of concern to a reasonable and prudent person relying upon the representation or statement in making a decision. The same principle applies to fraudulent half-truths or omissions of material facts.

The representations which the government charges were made as part of the scheme to defraud are set forth in the indictment. It is not required that every misrepresentation or omission charged in the indictment be proved. It is sufficient if the prosecution proves beyond a reasonable doubt that one or more of the alleged material misrepresentations or omissions were made in furtherance of the alleged scheme to defraud.

In addition to proving that a statement was false or fraudulent and related to a material fact, in order to establish a scheme to defraud, the government must prove that the alleged scheme contemplated depriving another of money or property.

However, the government is not required to prove that the defendant personally originated the scheme to defraud. Furthermore, it is not necessary that the government prove that the defendant actually realized any gain from the scheme or that the intended victim actually suffered any loss. In this case, it so happens that the government does contend that the proof establishes that persons were defrauded and that the defendant profited. Although whether or not the scheme actually succeeded is really not the question, you may consider whether it succeeded in determining whether the scheme existed.

A scheme to defraud need not be shown by direct evidence, but may be established by all of the circumstances and facts in the case.

If you find that the government has sustained its burden of proof that a scheme to defraud, as charged, did exist, you next should consider the second element.

Authority: Sand, Modern Federal Jury Instructions, § 44-4; United States v. Males, 459 F.3d 154 (2d Cir. 2006); United States v. DiNome, 86 F.3d 277 (2d Cir. 1996).

REQUEST NO. 4

Second Element of Mail Fraud: Participation in Scheme with Intent

The second element that the government must prove beyond a reasonable doubt is that the defendant participated in the scheme to defraud knowingly, willfully, and with specific intent to defraud.

“Knowingly” means to act voluntarily and deliberately, rather than mistakenly or inadvertently.

“Willfully” means to act knowingly and purposely, with an intent to do something the law forbids; that is to say, with bad purpose either to disobey or to disregard the law.

“Intent to defraud” means to act knowingly and with the specific intent to deceive, for the purpose of causing some financial or property loss to another.

The question of whether a person acted knowingly, willfully, and with intent to defraud, is a question of fact for you to determine, like any other fact question. This question involves one’s state of mind.

Direct proof of knowledge and fraudulent intent is almost never available. It would be a rare case where it could be shown that a person wrote or stated that as of a given time in the past he committed an act with fraudulent intent. Such direct proof is not required. The ultimate facts of knowledge and criminal intent, though subjective, may be established by circumstantial evidence, based upon a person’s outward manifestations, his or her words, his or her conduct, his or her acts, and all the surrounding circumstances disclosed by the evidence and the rational or logical inferences that may be drawn from them.

Circumstantial evidence, if believed, is of no less value than direct evidence. In either case, the essential elements of the crime must be established beyond a reasonable doubt.

Since an essential element of the crime charged is intent to defraud, it follows that good faith on the part of the defendant is a complete defense to a charge of mail fraud. The defendant, however, has no burden to establish a defense of good faith. The burden is on the government to prove fraudulent intent and the consequent lack of good faith beyond a reasonable doubt.

Under the mail fraud statute, even false representations or statements, or omissions of material facts, do not amount to a fraud unless done with fraudulent intent. However misleading or deceptive a plan may be, it is not fraudulent if it was devised or carried out in good faith. An honest belief in the truth of the representations made by a defendant is a good defense, however inaccurate the statements may turn out to be.

There is another consideration to bear in mind in deciding whether or not defendant acted in good faith. You are instructed that if the defendant participated in the scheme to defraud, then a belief by the defendant, if such belief existed, that ultimately everything would work out so that no one would lose any money does not require a finding by you that the defendant acted in good faith. If the defendant participated in the scheme for the purpose of causing some financial or property loss to another, then no amount of honest belief on the part of the defendant that the scheme would work out will excuse fraudulent actions or false representations by him.

As a practical matter, then, in order to sustain the charges against the defendant, the government must establish beyond a reasonable doubt that he knew that his conduct as a participant in the scheme was calculated to deceive and, nonetheless, he associated himself with the alleged fraudulent scheme for the purpose of causing some loss to another.

The government may prove that the defendant acted knowingly in either of two ways. First, it is sufficient, of course, if the evidence satisfies you beyond a reasonable doubt that the defendant was actually aware he or she was making a false statement or causing a false statement

to be made. Alternatively, in determining whether the defendant acted knowingly, you may consider whether the defendant deliberately closed their eyes to what would otherwise have been obvious to them and acted with a conscious purpose to avoid learning the truth. Thus, if you find beyond a reasonable doubt, that the defendant was aware of a high probability that the statement was false, and acted with deliberate disregard for the truth, you may find that the defendant acted knowingly. This guilty knowledge, however, cannot be established by demonstrating merely negligence or foolishness on the part of the defendant.

To conclude, on this element, if you find that the defendant was not a knowing participant in the scheme, or that he lacked the specific intent to defraud, you should find the defendant not guilty. On the other hand, if you find that the government has established beyond a reasonable doubt not only the first element, namely, the existence of the scheme to defraud, but also this second element, that the defendant was a knowing participant and acted with specific intent to defraud, and if the government also establishes the third element, as to which I am about to instruct you, then you have a sufficient basis upon which to convict the defendant.

Authority: Sand, Modern Federal Jury Instruction, § 44-5; United States v. DiNome, 86 F.3d 277 (2d Cir. 1996).

REQUEST NO. 5

Third Element of Mail Fraud: Use of the Mails

The third and final element that the government must establish beyond a reasonable doubt is the use of the mails in furtherance of the scheme to defraud. The use of the mails as I have used it here includes material sent through either the United States Postal Service or a private or commercial interstate carrier such as UPS or Federal Express.

The mailed matter need not contain a fraudulent representation or purpose or request for money. It must, however, further or assist in the carrying out of the scheme to defraud.

It is not necessary for the defendant to be directly or personally involved in the mailing, as long as the mailing was reasonably foreseeable in the execution of the alleged scheme to defraud in which the defendant is accused of participating. In this regard, it is sufficient to establish this element of the crime, if the evidence justifies a finding that the defendant caused the mailing by others. This does not mean that the defendant must specifically have authorized others to do the mailing. When one does an act with knowledge that the use of the mails will follow in the ordinary course of business or where such use of the mails can reasonably be foreseen, even though not actually intended, then he causes the mails to be used.

With respect to the use of the mails, the government must establish beyond a reasonable doubt the particular mailing charged in the indictment. However, the government does not have to prove that the mailings were made on the exact date charged in the indictment. It is sufficient if the evidence establishes beyond a reasonable doubt that the mailing was made on a date substantially similar to the date charged in the indictment.

Authority: Sand, Modern Federal Jury Instruction, § 44-6

REQUEST NO. 6

Counts 2-18: Wire Fraud (18 U.S.C. §1343)

The next counts I want to talk to you about are Counts Two through Eighteen of the indictment, which charge the defendant with wire fraud. Counts Two through Eighteen read, in relevant part, as follows.

On or about the dates set forth below, within the Eastern District of New York and elsewhere, the defendant WILLIAM SCULLY, also known as 'Liam Scully,' together with others, did knowingly and intentionally devise a scheme and artifice to defraud customers of MDK, and to obtain money and property from them, by means of materially false and fraudulent pretenses, representations and promises, and for the purpose of executing and attempting to execute such scheme and artifice, cause writings, signals, pictures and sounds to be transmitted by means of wire communication in interstate and foreign commerce, as set forth below

The relevant statute on this subject is section 1343 of Title 18 of the United States Code.

It provides:

Whoever, having devised or intending to devise any scheme or artifice to defraud, or for obtaining money or property by means of false or fraudulent pretenses, representations, or promises, transmits or causes to be transmitted by means of wire . . . communication in interstate or foreign commerce, any writings, signs, signals, pictures, or sounds for the purpose of executing such scheme or artifice, shall be [punished according to law].

In order to prove the defendant guilty of wire fraud, the government must prove each of the following elements beyond a reasonable doubt:

First, that there was a scheme or artifice to defraud or to obtain money or property by materially false and fraudulent pretenses, representations, or promises, as alleged in the indictment;

Second, that the defendant knowingly and willfully participated in the scheme or artifice to defraud with knowledge of its fraudulent nature and with specific intent to defraud or that he knowingly and intentionally aided and abetted others in the scheme; and

Third, that in the execution of that scheme, the defendant used or caused the use of interstate wires as specified in the indictment.

The first two elements for wire fraud are the same as the first two elements for mail fraud that I just explained to you. You must apply those instructions to the first two elements of the wire fraud counts. If you find that the government has established beyond a reasonable doubt those same first two elements with respect to any wire charge, you should consider the third element of the wire fraud charge.

Authority: Sand, Modern Federal Jury Instruction, §§ 44-1, 44-3, 44-4, 44-5.

REQUEST NO. 7

Third Element of Wire Fraud: Use of the Wires

The third and final element that the government must establish beyond a reasonable doubt is the use of an interstate or international wire communication in furtherance of the scheme to defraud.

The wire communication must pass between two or more states as, for example, a telephone call between New York and New Jersey; or it must pass between the United States and a foreign country, such as a telephone call between New York and Turkey. A wire communication also includes a wire transfer of funds between banks in different states or between a bank in the United States and a bank in a foreign country.

The use of wires need not itself be a fraudulent representation. It must, however, further or assist in the carrying out of the scheme to defraud.

It is not necessary for the defendant to be directly or personally involved in the wire communication, as long as the communication was reasonably foreseeable in the execution of the alleged scheme to defraud in which the defendant is accused of participating.

In this regard, it is sufficient to establish this element of the crime if the evidence justifies a finding that the defendant caused the wires to be used by others. This does not mean that the defendant must specifically have authorized others to make the call or transfer the funds. When one does an act with knowledge that the use of the wires will follow in the ordinary course of business or where such use of the wires can reasonably be foreseen, even though not actually intended, then he causes the wires to be used. The government contends that it was reasonably foreseeable that the wires, including telephone calls, facsimiles and emails, would be used in the

ordinary course of business to communicate with customers and transfer money, and therefore that the defendant caused the use of the wires.

With respect to the use of the wires, the government must establish beyond a reasonable doubt the particular use charged in the indictment. However, the government does not have to prove that the wires were used on the exact date charged in the indictment. It is sufficient if the evidence establishes beyond a reasonable doubt that the wires were used on a date substantially similar to the dates charged in the indictment.

Authority: Sand, Modern Federal Jury Instructions, § 44-7.

REQUEST NO. 8

Count 1: Conspiracy to Commit Wire Fraud (18 U.S.C. 1349)

Count 19: Conspiracy to Commit Mail Fraud (18 U.S.C. 1349)

Counts One and Nineteen of the indictment charge the defendant with Conspiracy to Commit Mail and Wire Fraud, respectively.

Count One reads as follows:

In or about and between February 2009 and July 2013, both dates being approximate and inclusive, within the Eastern District of New York and elsewhere, the defendant WILLIAM SCULLY, also known as 'Liam Scully,' together with others, did knowingly and intentionally conspire to devise a scheme and artifice to defraud customers of Pharmalogical and MDK, and to obtain money from them by means of materially false and fraudulent pretenses, representations and promises, and for the purpose of executing such scheme and artifice, to transmit and cause to be transmitted, by means of wire and radio communication in interstate and foreign commerce, writings, signs, signals, pictures and sounds, contrary to Title 18, United States Code, Section 1343.

Count Nineteen reads as follows:

In or about and between February 2009 and July 2013, within the Eastern District of New York and elsewhere, the defendant WILLIAM SCULLY, also known as 'Liam Scully,' together with others, did knowingly and intentionally conspire to devise a scheme and artifice to defraud customers of Pharmalogical and MDK, and to obtain money and property from them by means of materially false and fraudulent pretenses, representations and promises and, for the purpose of executing such scheme and artifice, did cause to be delivered by private commercial interstate carriers one or more mail matters and things, to wit: packages containing misbranded drugs, according to the directions thereon, contrary to Title 18, United States Code, Section 1341.

The statute the defendant is charged with violating is section 1349 of Title 18 of the United States Code. Section 1349 provides, in relevant part:

Any person who attempts or conspires to commit any offense under this chapter shall be subject to the same penalties as those

prescribed for the offense, the commission of which was the object of the attempt or conspiracy.

A conspiracy is a criminal partnership: an agreement by two or more persons to join together to violate the law. The crimes of conspiracy to commit mail fraud and conspiracy to commit wire fraud are independent crimes. They are entirely separate and different offenses from the underlying crimes the defendant is alleged to have agreed to commit. You may therefore find the defendant guilty of the crime of conspiracy, even if any of the substantive crimes that were the object of the conspiracies, here, mail and wire fraud, were not actually committed.

In order to prove the crime of conspiracy, the government must establish the following three elements of the crime beyond a reasonable doubt:

First, that two or more persons entered into the particular unlawful agreement charged in the indictment starting on or about February 1, 2009;

Second, that the objective of the conspiracy was to commit at least one of the unlawful acts charged in the indictment;

Third, that the defendant knowingly, intentionally, and willfully became a member of the conspiracy.

Authority: Adopted from the charge of the Hon. Nina Gershon, United States v. Stinn, 07 CR 113 (E.D.N.Y.); charge of the Hon. Sandra J. Feuerstein, United States v. Juncal, 06 CR 0264 (E.D.N.Y.); charge of the Hon. I. Leo Glasser, United States v. Mahaffy, 05 CR 613 (E.D.N.Y.); charge of the Hon. Frederic Block, United States v. Bahlay, 98 CR 135 (E.D.N.Y.).

REQUEST NO. 9

First Element: Agreement

The first element which the government must prove beyond a reasonable doubt to establish the offense of conspiracy is that two or more persons entered the unlawful agreement charged in the indictment.

In order for the government to satisfy this element, you need not find that the alleged members of the conspiracy met together and entered into any express or formal agreement. Similarly, you need not find that the alleged conspirators stated, in words or writing, what the scheme was, its object or purpose, or every precise detail of the scheme or the means by which its object or purpose was to be accomplished. What the government must prove is that there was a mutual understanding, either spoken or unspoken, between two or more people to cooperate with each other to accomplish an unlawful act.

You may, of course, find that the existence of an agreement to disobey or disregard the law, has been established by direct proof. However, since conspiracy is, by its very nature, characterized by secrecy, direct proof may not be available. Therefore, you are permitted to infer the existence of a conspiracy from the circumstances and the conduct of the parties involved. In a very real sense, then, in the context of conspiracy cases, actions often speak louder than words. In this regard, you may, in determining whether an agreement existed here, consider the actions and statements of all of those you find to be participants as proof that a common design existed on the part of the persons charged to act together to accomplish an unlawful purpose.

Authority: Sand, Modern Federal Jury Instructions, § 19-4.

REQUEST NO. 10

Second Element: Unlawful Acts

The second element that the government must prove beyond a reasonable doubt is that the objective of the conspiracy was to commit at least one of the unlawful acts charged in the indictment.

If you find unanimously that two or more persons agreed to commit any one of these objectives, then this element would be proved. That is, it is not enough to convict if some of you find that the government has proven only an agreement to accomplish one unlawful objective while others of you find that the government has proven an agreement to accomplish a different unlawful objective.

Authority: Adopted from the charge of the Hon. Nina Gershon, United States v. Stinn, 07 CR 113 (E.D.N.Y.); charge of the Hon. Sandra J. Feuerstein, United States v. Juncal 06 CR 0264 (E.D.N.Y.); charge of the Hon. I. Leo Glasser, United States v. Mahaffy, 05 CR 613 (E.D.N.Y.); charge of the Hon. Frederic Block, United States v. Bahlay, 98 CR 135 (E.D.N.Y.).

REQUEST NO. 11

Third Element: Membership in the Conspiracy

The third element that the government must prove beyond a reasonable doubt is that the defendant knowingly, intentionally, and willfully became a member of the charged conspiracies. If you are satisfied that the conspiracies charged in the indictment existed, you must next ask yourselves who the members of that conspiracies were. In deciding whether the defendant whom you are considering was, in fact, a member of the conspiracies, you should consider whether the defendant knowingly and willfully joined the conspiracies. Did he participate in it with knowledge of its unlawful purpose and with the specific intention of furthering its business or objective as an associate or worker?

In that regard, it has been said that in order for a defendant to be deemed a participant in a conspiracy, he or she must have had a stake in the venture or its outcome. You are instructed that, while proof of a financial interest in the outcome of a scheme is not essential, if you find that the defendant had such an interest then that is a factor which you may properly consider in determining whether or not the defendant was a member of the conspiracies charged in the indictment.

As I mentioned a moment ago, before the defendant can be found to have been a conspirator, you must first find that he or she knowingly joined in the unlawful agreement or plan. The key question, therefore, is whether the defendant joined the conspiracies with an awareness of at least some of the basic aims and purposes of the unlawful agreement.

It is important for you to note that the defendant's participation in the conspiracies must be established by independent evidence of his own acts or statements, as well as those of the other alleged co-conspirators, and the reasonable inferences which may be drawn from them.

The defendant's knowledge is a matter of inference from the facts proved. In that connection, I instruct you that to become a member of the conspiracies, the defendant need not have known the identities of each and every other member, nor need he or she have been appraised of all of their activities. Moreover, the defendant need not have been fully informed as to all of the details, or the scope, of the conspiracies in order to justify an inference of knowledge on his part. Furthermore, the defendant need not have joined in all of the conspiracies' unlawful objectives.

The extent of a defendant's participation has no bearing on the issue of a defendant's guilt. A conspirator's liability is not measured by the extent of duration of his participation. Indeed, each member may perform separate and distinct acts and may perform them at different times. Some conspirators play major roles, while others play minor parts in the scheme. An equal role is not what the law requires. In fact, even a single act may be sufficient to draw the defendant within the ambit of the conspiracies.

I want to caution you, however, that mere presence at a place where criminal conduct is under way does not, by itself, make a person a member of a conspiracy to commit that crime. Similarly, mere association with one or more members of the conspiracies does not automatically make the defendant a member. A person may know, or be friendly with, a criminal without himself being a criminal. Mere similarity of conduct or the fact that they may have been assembled together and discussed common aims and interests does not necessarily establish membership in the conspiracies.

I also want to caution you that mere knowledge or acquiescence, without participation, in the unlawful plan is not sufficient. Moreover, the fact that the acts of a defendant, without knowledge, merely happen to further the purposes or objectives of the conspiracies does not

make the defendant a member. More is required under the law. What is necessary is that the defendant must have participated with knowledge of at least some of the purposes or objectives of the conspiracies and with the intention of aiding in the accomplishment of those unlawful ends.

In sum, the defendant, with an understanding of the unlawful character of the conspiracies must have intentionally engaged, advised, or assisted in it for the purpose of furthering the illegal undertaking. He thereby becomes a knowing and willing participant in the unlawful agreement, that is to say, a conspirator.

Authority: Sand, Modern Federal Jury Instructions, § 19-6. Adopted from the charge of the Hon. Nina Gershon, United States v. Stinn, 07 CR 113 (E.D.N.Y.); charge of the Hon. Sandra J. Feuerstein, United States v. Juncal, 06 CR 0264 (E.D.N.Y.); charge of the Hon. I. Leo Glasser, United States v. Mahaffy, 05 CR 613 (E.D.N.Y.); charge of the Hon. Frederic Block, United States v. Bahlay, 98 CR 135 (E.D.N.Y.).

REQUEST NO. 12

The Food, Drug and Cosmetic Act

This is a criminal prosecution arising in part under the Federal Food, Drug, and Cosmetic Act, Title 21, United States Code, Sections 301-397, which has as its underlying purpose the protection of the public health and welfare, including the protection of consumers, who in circumstances of modern society, are unable to protect themselves either from drugs that may not be safe and effective for their intended uses or from drugs that bear labels that do not contain adequate directions and warnings or are not easily understood. I will hereafter refer to the Federal Food, Drug, and Cosmetic Act as the "FDCA."

Authority: Adapted from Jury Charge of Hon. Jose Gonzalez, Jr., United States v. Van Moor, 06-CR-60064 (S.D. Fla.).

REQUEST NO. 13

Counts 38-54: Introduction of Misbranded Drugs into Interstate Commerce
(21 U.S.C. 331(a), 333(a)(2))

Counts Thirty-Eight through Fifty-Four of the indictment charge that the defendant, with the intent to defraud or mislead, introduced or caused the introduction of misbranded drugs into interstate commerce, in violation of Title 21, United States Code, Sections 331(a) and 333(a)(2).

Counts Thirty-Eight through Fifty-Four read as follows:

On or about the dates as set forth below, within the Eastern District of New York and elsewhere, the defendant WILLIAM SCULLY, also known as "Liam Scully," together with others, did knowingly and intentionally introduce and cause to be introduced into interstate commerce, with the intent to defraud and mislead, one or more misbranded drugs . . .

The statutes defendant is charged with violating are sections 331(a) and 333(a)(2) of Title 21 of the United States Code. Section 331(a) provides, in relevant part:

The following acts and the causing thereof are prohibited: (a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded.

Section 333(a)(2) of Title 21 of the United States Code provides, in relevant part:

(a) Violation of section 331 of this title; second violation; intent to defraud or mislead . . . (2) Notwithstanding the provisions of paragraph (1) of this section, if any person commits such a violation after a conviction of him under this section has become final, or commits such a violation with the intent to defraud or mislead, such person shall be [punished according to law].

I will instruct you momentarily on the four ways in which the drugs are alleged to have been misbranded within the meaning of Title 21, United States Code, Section 352. In order for the Defendant to be found guilty of the charges in Counts Thirty-Eight through Fifty-Four, the Government must prove beyond a reasonable doubt each of the following elements:

First: That the products were drugs, as I will define that term;

Second: That the defendant introduced or caused the introduction of the drugs into “interstate commerce,” as I will explain that term momentarily;

Third: That the drugs were misbranded, as I will explain that term momentarily;

Fourth: That the defendant acted with the intent to defraud or mislead.

Authority: Adapted from Jury Charge of Hon. Jose Gonzalez, Jr., United States v. Van Moor, 06-CR-60064 (S.D. Fla.).

REQUEST NO. 14

Definition of Drug

You are instructed that an article is a "drug" under the FDCA if it is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man, or if it is intended to affect the structure or any function of the human body. It is the intended use of a substance which determines whether it is a drug under the FDCA, and not the nature or composition of the article, or whether and how the article actually affects the structure or any function of the human body.

You can determine the intended use of a product by considering the label, accompanying labeling, promotional material, advertising, oral representations made about the product, the circumstances surrounding the distribution of the article, and information from any other source which discloses intended use. The mere use of the name of the product can be a claim to diagnose, mitigate, treat, cure, or prevent disease. You are not bound by any particular claims or statements made by the manufacturer or seller disclaiming an intended use if there is other evidence concerning intended use that conflicts with those claims or statements.

If you find that the defendant intended for these products to be used for the diagnosis, cure, mitigation, treatment, or prevention of a disease, then you must find that the product is a drug under the FDCA.

Authority: Adapted from Jury Charge of Hon. Jose Gonzalez, Jr., United States v. Van Moor, 06-CR-60064 (S.D. Fla.); 21 U.S.C. § 321(g)(1); 21 C.F.R. § 201.128. United States v. Livdahl, 459 F. Supp. 2d 1255, 1259-60 (S.D.Fla. 2005); United States v. An Article, 409 F.2d 734, 739 (2d Cir. 1969); United States v. Hohensee, 243 F.2d 367, 370 (3d Cir. 1957) (citing Kordel v. United States, 335 U.S. 345, 69 S.Ct. 106 (1948)); Nature Food Centers, Inc. v. United States, 310 F.2d 67 (1st Cir. 1963); United States v. Article of Drug Designated B-Complex Cholinol Capsules, 362 F.2d 923 (3d Cir. 1966).

REQUEST NO. 15

Definition of Interstate Commerce

Counts Thirty-Eight through Fifty-Four of the indictment allege that the defendant introduced or caused the introduction of misbranded drugs into "interstate commerce." "Interstate commerce" means commerce between any State and any place outside thereof. If you find that for Counts 38-54 defendant caused the introduction of the drug products from one state or country to another, for example, from Ireland to New York, or from New York to Nevada, then you must find that products identified in that count were in interstate commerce.

Authority: 21 U.S.C. § 321(b); Adapted from Jury Charge of Hon. Jose Gonzalez, Jr., United States v. Van Moor, 06-CR-60064 (S.D. Fla.); Hipolite Egg Co. v. United States, 220 U.S. 45, 54 (1911); United States v. Wiesenfeld Warehouse Co., 376 U.S. 86 (1964).

REQUEST NO. 16

Definition of Intent to Defraud or Mislead

Counts Thirty-Seven through Seventy-One, Seventy-Four and Seventy-Five, allege that the defendant violated, or agreed to violate, provisions of the FDCA with the intent to defraud or mislead. "Intent to defraud" means to act with the specific intent to deceive or cheat, ordinarily for the purpose of either causing some financial loss to another or bringing about some financial gain to one's self. It is not necessary, however, to prove that anyone was, in fact, defrauded as long as it is established beyond a reasonable doubt that the defendant acted with the intent to defraud. You are instructed that to act with "intent to mislead" means to act with the specific intent to create a false impression by misstating, misrepresenting, omitting, or concealing facts. It is not necessary, however, to prove that anyone was, in fact, misled as long as it is established beyond a reasonable doubt that the defendant acted with the intent to mislead.

A defendant acts with intent to defraud or mislead under the FDCA if the defendant acts with the intent to defraud or mislead either (1) the consumers of the defendant's products or (2) the government. You must all agree on whether the defendant acted with the intent to defraud or mislead consumers or the government. You may also unanimously find that the defendant acted with the intent to defraud or mislead both consumers and the government, but only one of them is necessary to satisfy this element.

To act with the intent to defraud or mislead the consumers of a product means to act with the specific intent to mislead either the direct purchaser of the product, or subsequent purchasers or users, about the nature of the product being used or purchased or some significant fact or aspect of the product being used or purchased.

To act with the intent to defraud or mislead the government means to act with the specific intent to interfere with or obstruct a lawful government function by deceit, craft or trickery, or at least by means that are dishonest. Intent to defraud or mislead the government can be established by proof beyond a reasonable doubt that the defendant took affirmative steps in an effort to conceal his activities from government agencies, such as the FDA, charged with regulating those activities.

Ordinarily, there is no way that a defendant's state of mind can be proved directly, because no one can read another person's mind and tell what that person is thinking. But a defendant's state of mind can be proved indirectly from the surrounding circumstances. This includes things such as what the defendant said, what the defendant did, how the defendant acted, and any other facts or circumstances in evidence that bear on the defendant's intent.

Authority: 21 U.S.C. § 333(a)(2); Adapted from Jury Charge of Hon. Jose Gonzalez, Jr., United States v. Van Moor, 06-CR-60064 (S.D. Fla.); United States v. Bradshaw, 840 F.2d 871, 874 (11th Cir.), cert. denied, 488 U.S. 924 (1988); United States v. Cambra, 933 F.2d 752 (9th Cir. 1991); United States v. Arlen, 947 F.2d 139, (5th Cir. 1991); United States v. Mitcheltree, 940 F.2d 1329, 1349 (10th Cir. 1991); United States v. Orrego Martinez, 575 F.3d 1 (1st Cir. 2009); United States v. Milstein, 401 F.3d 53 (2d Cir. 2005); United States v. Ellis, 326 F.3d 550, 554 (4th Cir. 2003); United States v. Arlen, 947 F.2d 139, (5th Cir. 1991).

REQUEST NO. 17

Misbranding: Four Different Ways

As I previously explained, Counts Thirty-Eight through Fifty-Four charge that the defendant, with the intent to defraud or mislead, caused products to be introduced into interstate commerce that were misbranded in four distinct ways. You do not need to find that the products were misbranded in all of the four ways in order to find the defendant guilty. The element of misbranding is satisfied if you find beyond a reasonable doubt that the products were misbranded in at least one of the four ways, but you must all agree on at least one particular way that each product was misbranded.

Authority: 21 U.S.C. § 352; Adapted from Jury Charge of Hon. Jose Gonzalez, Jr., United States v. Van Moor, 06-CR-60064 (S.D. Fla.).

REQUEST NO. 18First Way of Misbranding

First, a drug is misbranded within the meaning of Title 21, United States Code, Section § 352(a), if its labeling is false or misleading in any particular. The FDCA has distinct definitions for the terms "label" and "labeling." The term "label" means a display of written, printed, or graphic matter upon the immediate container of any article. The term "labeling" means all labels and other written, printed, or graphic matter that appears on any product or on any of its containers or wrappers, or that accompanies the product. Thus, the term "labeling" is broader than the term "label," and "labels" are but one kind of "labeling." It is unnecessary for the matter to have been physically attached to the drug or to have been shipped at the same time or with the drug to constitute "labeling." Under the FDCA, as I just explained, such matter can constitute "labeling" if it "accompanies the product." If such matter is provided as part of an integrated distribution program pertaining to a drug and explains the uses of the drug, then it "accompanies" the drug and constitutes "labeling." For example, information on a company's website can constitute "labeling" if such information is provided as part of an integrated distribution program with respect to the drug.

You do not need to find that the labeling is false or misleading in its entirety. You need only find that any single representation in the labeling is false or misleading, with all of you agreeing as to the particular representation in which the labeling is false or misleading.

Authority: Adapted from Jury Charge of Hon. Jose Gonzalez, Jr., United States v. Van Moor, 06-CR-60064 (S.D. Fla.); 21 U.S.C. §§ 352(a), 321(l) and (m); United States v. Kordel, 335 U.S. 345 (1948); United States v. Urbuteit, 335 U.S. 355 (1948); United States v. Hoxsey Cancer Clinic, 198 F.2d 273, 281 (5th Cir. 1952); United States v. Sene X Eleemosynary Corp., 479 F.Supp. 970, 980 (S.D. Fla. 1979); United States v. Walton, 36 F.3d 32 (7th Cir. 1994); United States v. 47 Bottles...Jenosol RJ Formula >60, 320 F.2d 564, 568-70 (3d Cir. 1963); United

States v. 4 Devices, Labeled in Part "Color-Therm," 176 F.2d 652, 654 (10th Cir. 1949); United States v. Kasz Enterprises, 855 F. Supp. 534, 539-41 (D.R.I. 1994); United States v. An Article or Device ... "Hubbard Electrometer," 333 F. Supp. 357 (D.D.C. 1971); United States v. 250 Jars, etc. of U.S. Fancy Pure Honey, 218 F. Supp. 208 (E.D. Mich. 1963), aff'd, 344 F.2d 288 (6th Cir. 1965); United States v. 8 Cartons, Containing "Plantation, 'The Original,' etc., Molasses," 103 F. Supp. 626 (W.D.N.Y. 1951); United States v. Berst, 2012 WL 4361408.

REQUEST NO. 19

Second Way of Misbranding

Second, a drug is misbranded within the meaning of Title 21, United States Code, Section 352(c), if all information required by or under authority of the FDCA does not appear on the label or labeling in the English language, thereby rendering the information unlikely to be read and understood by the ordinary individual under customary conditions of purchase and use of the products in the United States.

Authority: 21 U.S.C. § 352(c); 21 C.F.R. § 201.15(c)(1).

REQUEST NO. 20

Third Way of Misbranding

Third, a drug is misbranded within the meaning of Title 21, United States Code, Section 353(b)(4)(A) if it is a prescription drug and the label of the drug fails to bear the symbol “Rx only” at any time prior to dispensing. A prescription drug is a drug intended for use by man which because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or is limited by an approved application under Section 505 of the FDCA for use under the professional supervision of a practitioner licensed by law to administer such drug.

Authority: 21 U.S.C. § 353(b).

REQUEST NO. 21Fourth Way of Misbranding

Fourth, a drug is misbranded within the meaning of Title 21, United States Code, Section 352(f)(1) if its labeling lacks adequate directions for use. I previously have explained to you about the meaning of the term "labeling" under the FDCA. As with the term "labeling," the term "adequate directions for use" has a specific meaning under the FDCA. "Adequate directions for use" under the FDCA means directions sufficient to enable a layman to use a drug safely and for the purposes for which it is intended. Directions for use may be inadequate because they omit statements of conditions, purposes, or uses for which the drug is commonly used. Directions for use may also be inadequate if they fail to give the quantity of dose and the frequency, duration, time, and route of administration. No drug can be said to contain in its labeling "adequate directions for its use," unless every ailment of the body for which it is, through any means, held out to the public as an effective remedy is listed in the labeling, together with instructions to the user concerning quantity and frequency of dosage recommended for each particular ailment.

In addition, any directions for use that appear on the labeling of a prescription drug that is an unapproved new drug, as defined in these instructions, are per se inadequate because that labeling has never been approved by FDA in the context of an approved marketing application. In that case, the government need not present any additional evidence to establish that the directions for use on the drug's labeling were inadequate.

Authority: 21 C.F.R. §§ 201.100(c)(2) and 201.5; Adapted from Jury Charge of Hon. Jose Gonzalez, Jr., United States v. Van Moor, 06-CR-60064 (S.D. Fla.); United States v. Baxter Healthcare Corp., 712 F. Supp. 1352, 1359 (N.D. Ill. 1989), aff'd, 901 F.2d 1401 (7th Cir. 1990); United States v. 225 Cartons ... Fiorinal, 687 F. Supp. 946, 962 (D.N.J. 1988), aff'd, 871 F.2d 409 (3d Cir. 1989); United States v. Articles of Drug, Foods Plus, Inc., 239 F. Supp. 465 (D.N.J. 1965), remanded on other grounds, 362 F.2d 923 (3d Cir. 1966).

REQUEST NO. 22

Count 37: Conspiracy to Distribute Misbranded Drugs (18 U.S.C. § 371)

The thirty-seventh count in the indictment charges the defendant with Conspiracy to Distribute Misbranded Drugs. Count Thirty-Seven reads as follows:

In or about and between February 2009 and July 2013, both dates being approximate and inclusive, within the Eastern District of New York and elsewhere, the defendant WILLIAM SCULLY, also known as 'Liam Scully,' together with others, did knowingly and willfully conspire to introduce and deliver for introduction into interstate commerce, with the intent to defraud and mislead, drugs that were misbranded, contrary to Title 21, United States Code, Sections 331(a) and 333(a)(2).

The statute the defendant is charged with violating is section 371 of Title 18 of the United States Code. Section 371 provides, in relevant part:

If two or more persons conspire either to commit any offense against the United States, or to defraud the United States, or any agency thereof in any manner or for any purpose, and one or more of such persons do any act to effect the object of the conspiracy, each shall be [punished according to law].

As I explained previously, a conspiracy is a criminal partnership: an agreement by two or more persons to join together to violate the law. The crime of conspiracy to distribute misbranded drugs is an independent crime. It is an entirely separate and different offense from the underlying crime the defendant is alleged to have agreed to commit. You may therefore find the defendant guilty of the crime of conspiracy even if the substantive crime that was the object of the conspiracy, here, introduction of misbranded drugs into interstate commerce with intent to defraud or mislead, was not actually committed.

Similar to the counts charging defendant with conspiracy to commit mail and wire fraud, in order to prove the crime of conspiracy to distribute misbranded drugs, the government must establish the following three elements of the crime beyond a reasonable doubt:

First, that the defendant agreed with at least one other person to defraud the United States or an agency thereof;

Second, that at some time during the existence or life of the conspiracy, agreement, or understanding, the defendant knew the purposes of the agreement;

Third, that with knowledge of the purposes of the conspiracy, agreement, or understanding, the defendant then deliberately joined the conspiracy, agreement, or understanding.

In addition, as to this conspiracy in which overt acts are alleged in the indictment, you must also find:

Fourth, that at some time during the existence or life of the conspiracy, agreement, or understanding, one of its alleged members knowingly performed one of the overt acts charged in the indictment and did so in order to further or advance the purposes of the agreement.

REQUEST NO. 23

Pinkerton Charge

There is another method by which you may evaluate the possible guilt of the defendant for mail fraud, wire fraud or introduction of misbranded drugs into interstate commerce with the intent to defraud or mislead, even if you do not find that the government has satisfied its burden of proof with respect to each element of those crimes.

If, in light of my instructions, you find, beyond a reasonable doubt, that the defendant was a member of the conspiracies charged in Counts 1, 19 or 37 of the indictment, and thus, guilty on one or more of the conspiracy counts, then you may also, but you are not required to, find him guilty of the corresponding substantive counts of mail fraud, wire fraud, introduction of misbranded drugs into interstate commerce with the intent to defraud or mislead, and receipt of misbranded drugs in interstate commerce, set forth in Counts 2-18, 20-36, 38-54 and 55-71, respectively, provided you find, beyond a reasonable doubt, each of the following elements:

First, that the crime charged in the substantive count was committed;

Second, that the person or persons you find actually committed the crime were members of the conspiracy you found to have existed;

Third, that the substantive crime was committed pursuant to the common plan and understanding you found to exist among the conspirators;

Fourth, that the defendant was a member of that conspiracy at the time the substantive crime was committed;

Fifth, that the defendant could have reasonably foreseen that the substantive crime might be committed by his co-conspirators.

If you find all five of these elements to exist beyond a reasonable doubt, then you may find the defendant guilty of mail fraud, wire fraud and introduction of misbranded drugs into interstate commerce with the intent to defraud or mislead, even though he did not personally participate in the acts constituting those crimes or did not have actual knowledge of it.

The reason for this rule is simply that a co-conspirator who commits a crime pursuant to a conspiracy is deemed to be the agent of the other conspirators. Therefore, all of the co-conspirators must bear criminal responsibility for the commission of the crimes committed by its members.

If, however, you are not satisfied as to the existence of any of these five elements, then you may not find the defendant guilty of mail fraud, wire fraud or introduction of misbranded drugs into interstate commerce, unless the government proves, beyond a reasonable doubt, that the defendant personally committed, or aided and abetted the commission of, those crimes.

Authority: Sand, Modern Federal Jury Instructions, § 19-13.

REQUEST NO. 24

Counts 55-71: Receipt of Misbranded Drugs in Interstate Commerce
(21 U.S.C. §§ 331(c), 333(a)(2))

The defendant is charged in Counts 55-71 of the indictment with receiving misbranded drugs in interstate commerce, and then delivering or proffering delivery of those drugs for pay or otherwise, with the intent to defraud or mislead, in violation of Title 21, Sections 331(c) and 333(a)(2) of the United States Code.

Counts Fifty-Five through Seventy-One read as follows:

On or about the dates set forth below, within the Eastern District of New York and elsewhere, the defendant WILLIAM SCULLY, also known as "Liam Scully," together with others, did knowingly and intentionally, and with the intent to defraud and mislead, receive in interstate commerce from locations outside the United States and cause the receipt in interstate commerce from locations outside the United States and cause the delivery and proffered delivery thereof for pay, to the locations listed below one or more drugs that were misbranded:

The statutes defendant is charged with violating are sections 331(c) and 333(a)(2) of Title 21 of the United States Code. Section 331(c) provides, in relevant part:

The following acts and the causing thereof are prohibited: . . . (c) The receipt in interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.

Section 333(a)(2) of Title 21 of the United States Code provides, in relevant part:

(a) Violation of section 331 of this title; second violation; intent to defraud or mislead . . . (2) Notwithstanding the provisions of paragraph (1) of this section, if any person commits such a violation after a conviction of him under this section has become final, or commits such a violation with the intent to defraud or mislead, such person shall be [punished according to law].

In order for the defendant to be found guilty of that charge, the government must prove beyond a reasonable doubt that the defendant, with the intent to defraud or mislead, received or caused the receipt of misbranded drugs in interstate commerce and then delivered or proffered delivery, or caused the delivery or proffered delivery, of the drugs for pay or otherwise.

Authority: 21 U.S.C. §§ 331(c), 333(a)(2).

REQUEST NO. 25

Count 72: Fraudulent Importation and Transportation of Goods
(18 U.S.C. § 545)

The defendant is charged in Count 72 of the indictment with fraudulently importing into the United States merchandise in violation of Section 545 of the United States Code. In order for the defendant to be found guilty of that charge, the government must prove beyond a reasonable doubt that the defendant fraudulently imported brought merchandise into the United States contrary to Title 21 Sections 331(a), (c) and (d), 352 (f)(1) and 355.

Count Seventy-Two reads as follows:

In or about and between February 2009 and July 2013, both dates being approximate and inclusive, within the Eastern District of New York and elsewhere, the defendant WILLIAM SCULLY, also known as “Liam Scully,” together with others, did (a) knowingly and wilfully, with intent to defraud the United States, smuggle, or clandestinely introduce or attempt to smuggle or clandestinely introduce into the United States any merchandise which should have been invoiced, or made out or passed, or attempted to pass, through the customhouse any false, forged, or fraudulent invoice, or other document or paper and (b) knowingly, intentionally and fraudulently import and bring into the United States merchandise contrary to law, and did receive, conceal, buy, sell and facilitate the transportation, concealment and sale of such merchandise after importation, to wit: misbranded drugs, knowing such merchandise to have been imported and brought into the United States contrary to law.

The statute defendant is charged with violating is section 545 of Title 18 of the United States Code. Section 545 provides, in relevant part:

Whoever knowingly and willfully, with intent to defraud the United States, smuggles, or clandestinely introduces or attempts to smuggle or clandestinely introduce into the United States any merchandise which should have been invoiced, or makes out or passes, or attempts to pass, through the customhouse any false, forged, or fraudulent invoice, or other document or paper; or

Whoever fraudulently or knowingly imports or brings into the United States, any merchandise contrary to law, or receives, conceals, buys, sells, or in any manner facilitates the transportation, concealment, or sale of such merchandise after importation, knowing the same to have been imported or brought into the United States contrary to law [shall be punished according to law] –

Proof of defendant's possession of such goods, unless explained to the satisfaction of the jury, shall be deemed evidence sufficient to authorize conviction for violation of this section.

Thus, you may find the defendant guilty of this charge either by finding that defendant brought in misbranded drugs, items contrary to law or that he brought in items with false documents or labels. You must also find that defendant did this knowingly and willfully intending to defraud the United States or an agency thereof.

If you find that defendant was in possession of drugs that were brought into the United States whether under a false document or contrary to law, you may but are not required to infer guilt from that evidence. This is a permissive inference you may make.

To be guilty of smuggling goods into the United States, the following essential elements must be satisfied:

EITHER

1. that the defendant imported or brought into the United States the merchandise in question;
2. that the defendant did so contrary to law; and
3. that the defendant knew the importation was contrary to law;

OR

1. that the merchandise in question was imported or brought into the United States;
2. that such merchandise was imported contrary to law;

3. that the defendant received, concealed, bought, or other facilitated the transportation, concealment., or sale of the merchandise in question; and
4. that the defendant knew such merchandise had been imported in the United States contrary to law.

The indictment charges the offense set out in both paragraphs of 18 U.S.C. § 545.

As to unlawful importation of merchandise, which does not require proof of intent to defraud the United States, that is charged in the alternative. There are two separate ways to commit this specific offense: unlawful importation of merchandise; or receiving, concealing, selling or buying or in any way facilitating, the sale of illegally imported merchandise.

Authority: See 1-23 Modern Federal Jury Instructions-Criminal P 23.02; 9th Circuit Model Jury Instructions 8.37; Adapted from Jury Charge of Hon. Jose Gonzalez, Jr., United States v. Van Moor, 06-CR-60064 (S.D. Fla.).

REQUEST NO. 26

Count 73: Trafficking in Counterfeit Drugs (18 U.S.C. 2320(a)(4), 2 and 3551)

In order to establish the criminal offense under 18 U.S.C. § 2320(a)(4), the government must prove: (1) that the defendant trafficked or attempted to traffic in drugs; (2) that such trafficking, or attempt to traffic, was intentional; and (3) a drug sold was counterfeit by label or by having no active ingredient.

Count Seventy-Three reads as follows:

On or about and between April 6, 2012 and April 24, 2012, both dates being approximate and inclusive, within the Eastern District of New York and elsewhere, the defendant WILLIAM SCULLY, also known as Liam Scully, together with others, did knowingly and intentionally traffic in one or more counterfeit drugs, to wit: prescription cancer drugs.

The statute defendant is charged with violating is section 2320(a)(4) of Title 18 of the United States Code. Section 2320(a)(4) provides, in relevant part:

Offenses. -- Whoever intentionally . . . (4) traffics in a counterfeit drug . . . shall be punished [according to law].

Willful blindness means the defendant deliberately closed his eyes to what otherwise would have been obvious to him concerning the fact in question. The government may prove the defendant's willful blindness through direct or circumstantial evidence, including that: the defendant purchased or sold goods after notice of potential infringement; the defendant knew that the victim distributed its goods only through authorized dealers, when the defendant and his supplier were not authorized dealers; the goods came from a questionable supplier; the defendant or his source used coded invoices for branded merchandise.

Authority: United States Attorney's Criminal Resource Manual 1704; United States v. Brodie, 403 F.3d 123, 132 (3d Cir. 2005); United States v. Hiltz, 14 Fed.Appx. 17 (1st Cir. 2001).

REQUEST NO. 27

Count 74: Introduction of Unapproved New Drugs into Interstate Commerce
(21 U.S.C. 331(d), 333(a)(2) and 355, 18 U.S.C. Sec 2)

Title 21, United States Code, Sections 331(d), 355(a), and 333(a)(2) make it a federal crime for anyone, with the intent to defraud or mislead, to introduce or cause the introduction or delivery for introduction into interstate commerce any unapproved new drug.

Count Seventy-Four reads as follows:

In or about and between February 2009 and July 2013, within the Eastern District of New York and elsewhere, the defendant WILLIAM SCULLY, also known as "Liam Scully," together with others, with the intent to defraud and mislead, introduced and delivered into interstate commerce, and caused to be introduced and delivered into interstate commerce new drugs that were in violation of Title 21, United States Code, Section 355, in that they were not the subject of an approved NDA, approved ANDA or effective IND on file with FDA, to wit: Mirena IUD, Remicade, Aclasta, Velcade, Vidaza, Implanon, Venofer, Zometa, Mabthera, Avonex, Aredia, Aloxi and Altuzan..

The statutes defendant is charged with violating are sections 331(d) and 333(a)(2) of Title 21 of the United States Code. Section 331(d) provides, in relevant part:

The following acts and the causing thereof are prohibited: . . . (d) The introduction or delivery for introduction into interstate commerce of any article in violation of section 344, 350d, 355, or 360bbb-3 of this title.

Section 333(a)(2) of Title 21 of the United States Code provides, in relevant part:

(a) Violation of section 331 of this title; second violation; intent to defraud or mislead . . . (2) Notwithstanding the provisions of paragraph (1) of this section, if any person commits such a violation after a conviction of him under this section has become final, or commits such a violation with the intent to defraud or mislead, such person shall be [punished according to law].

Count 74 charges that the defendant, on or about the dates charged, with the intent to defraud or mislead, unlawfully caused the introduction or delivery for introduction into interstate commerce of “new drugs,” as that term is defined later in these instructions, without approval to do so from the FDA. This count charges shipments of unapproved new drugs to several purchasers as a separate violation of the law. The purchasers and the shipment dates alleged are set forth in the indictment. In order to establish the offense in Count 74; the government must prove each of the following elements beyond a reasonable doubt:

First: that the defendant introduced the drugs or delivered the drugs, or caused the drugs to be introduced or delivered for introduction into interstate commerce on or about the dates charged in the indictment;

Second: that at the time each drug was introduced or delivered for introduction into interstate commerce, it was a "new drug," as that term is defined for you in these instructions;

Third: that the new drug did not have the approval required by law before such drugs may be marketed; and

Fourth: that the defendant acted with intent to defraud or mislead.

Authority: Adapted from Jury Charge of Hon. Jose Gonzalez, Jr., United States v. Van Moor, 06-CR-60064 (S.D. Fla.).

REQUEST NO. 28

Element Two: Definition of New Drug

I have previously provided to you in my instructions definitions for "interstate commerce" and "intent to defraud or mislead," see Instructions 15 & 16, and you should apply those same instructions here.

The term "new drug," pertinent here, is defined by the FDCA to mean: "any drug . . . the composition of which is such that such drug is not generally recognized, by experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof." If you find that the products were a "drug," as I have previously defined that term, and that the drug was not generally recognized by qualified experts as safe or effective when used as prescribed, recommended, or suggested in its labeling, you must find that the product was a "new drug."

In addition, a new drug could not be lawfully entered into interstate commerce unless an approved New Drug Application ("NDA"), Abbreviated New Drug Application ("ANDA"), or notice of claimed investigational exemption was on file for the drug with the FDA.

In order to prove that a product was a "new drug," the government in this case does not have to show that the product was "new" in the sense that it was recently made or, in fact, was unsafe or ineffective, but simply that the product was not generally recognized among qualified experts as having been adequately shown to be safe or effective when used in the manner prescribed, recommended, or suggested in its labeling.

Anecdotal and testimonial evidence from doctors or patients regarding the safety and/or efficacy of a new drug is not sufficient to meet the standards of the FDCA with respect to

establishing a new drug's safety and effectiveness. General recognition of safety and effectiveness cannot be based on clinical impressions of practicing physicians or patients, poorly controlled experiments, or isolated case reports, random experience, and reports lacking the details which permit scientific evaluation.

Authority: Adapted from Jury Charge of Hon. Jose Gonzalez, Jr., United States v. Van Moor, 06-CR-60064 (S.D. Fla.); 21 U.S.C. § 321(p); 21 U.S.C. § 355(a); United States v. Undetermined Quantities . . . Equidantin, 675 F.2d 994 (8th Cir. 1982); Premo Pharmaceutical Laboratories, Inc. v. United States, 629 F.2d 795 (2d Cir. 1980); Weinberger v. Hynson, Westcott, & Dunning, Inc., 412 U.S. 609, 618-19 (1973); Weinberger v. Bentex Pharmaceuticals, Inc., 412 U.S. 645, 652 (1972); United States v. An Article of Drug ... 4,680 Pails, 725 F.2d 476, 487 (5th Cir. 1984); Simeon Management Co. v. FTC, 579 F.2d 1137, 1142 (9th Cir. 1978); United States v. Naremcu, Inc., 553 F.2d 1138 (8th Cir. 1977); United States v. Wier, 281 F.2d 850 (5th Cir. 1960); United States v. Sene X Eleemosynary Corp., Inc., 479 F. Supp. 970, 977 (S.D. Fla. 1979); United States v. Articles of Food and Drug..., 444 F. Supp. 266, 274 (E.D. Wis. 1977)..

REQUEST NO. 29

Definitions of "General Recognition of Safety and Effectiveness"

A general recognition of a drug's effectiveness must be based on three conditions.

First, there must be substantial evidence of the products' effectiveness that would be sufficient to obtain FDA's approval for the products. "Substantial evidence" is evidence consisting of adequate and well-controlled investigations, including clinical investigations, upon which qualified experts can fairly and reasonably conclude that the products will have the effect it is represented to have.

Second, the "adequate and well-controlled investigations" must be published in the scientific literature so that they are made generally available to the community of qualified experts and are, thereby, subject to peer evaluation, criticism, and review. The published investigations must be of the safety and efficacy of the complete product – that is – the complete product, as opposed to some of the ingredients in the product. The absence of literature establishing the safety and effectiveness of the product is proof that the requisite general recognition does not exist. Anecdotal and testimonial evidence from doctors or patients regarding the safety and/or effectiveness of a new drug is not sufficient to meet the standards of the FDCA with respect to establishing the drug's safety and effectiveness. In addition, general recognition of safety and effectiveness cannot be based on clinical impressions of practicing physicians or patients, poorly controlled experiments, or isolated case reports, random experience, and reports lacking the details which permit scientific evaluation.

Third, there must be a consensus among qualified experts, based on adequate and well controlled published investigations of the product, that the product is safe and effective for each of its labeled ingredients. If you find that anyone of these three conditions fails to exist for the

products, then you must find that the product was not generally recognized and effective and, therefore, was a "new drug."

Authority: Adapted from Jury Charge of Hon. Jose Gonzalez, Jr., United States v. Van Moor, 06-CR-60064 (S.D. Fla.); Weinberger v. Hynson, Westcott, & Dunning, Inc., 412 U.S. 609, 618-19 (1973); Weinberger v. Bentex Pharmaceuticals, Inc., 412 U.S. 645, 652 (1972); United States v. An Article of Drug ... 4,680 Pills, 725 F.2d 476, 487 (5th Cir. 1984); United States v. Western Serum Co., 666 F.2d 335, 338 (9th Cir. 1982); United States v. Undetermined Quantities . . . Equidantin, 675 F.2d 994 (8th Cir. 1982); Simeon Mgmt. Corp. v. Federal Trade Commn, 579 F.2d 1137, 1143 (9th Cir. 1978); United States v. Naremco, Inc., 553 F.2d 1138 (8th Cir. 1977); United States v. Wier, 281 F.2d 850 (5th Cir. 1960); United States v. Sene X Eleemosynary Corp., Inc., 479 F. Supp. 970, 977 (S.D. Fla. 1979); United States v. Articles of Food and Drug..., 444 F. Supp. 266, 274 (E.D. Wis. 1977).

REQUEST NO. 30

New Drug – Identity of Drug and Approved Application

A drug is not the subject of an FDA-approved new drug application or abbreviated new drug application unless the drug product itself, including its composition, its manufacturer, the facility at which it is manufactured, the processes by which it is manufactured, and its labeling, are identical to those that are specified in an approved new drug application or abbreviated new drug application.

Authority: In re Canadian Import Antitrust Litigation, 470 F.3d 785, 789-90 (8th Cir. 2006); United States v. Genendo Pharmaceutical, N.V., 485 F.3d 958 (7th Cir. 2007).

REQUEST NO. 31

Count 75: Unlicensed Wholesale Distribution of Prescription Drugs
(21 U.S.C. §§ 353(e), 331(t), and 333(b)(1)(D))

The defendant is charged in Count 75 of the indictment with unlicensed wholesale distribution of prescription drugs in violation of Title 21 Sections 353(e), 331(t) and 333(b)(1)(D) of the United States Code.

Count Seventy-Five reads as follows:

In on or about and between June 2012 and July 2013, within the Eastern District of New York and elsewhere, the defendant WILLIAM SCULLY, also known as “Liam Scully,” together with others, through Taranis Medical Corp., knowingly engaged in the wholesale distribution of prescription drugs, to wit: Oxaliplatin, Velcade, Zometa, Venofer, Avastin, Mabthera, Remicade and Mirena IUDs and other prescription drugs in interstate commerce, contrary to Title 21, United States Code, Section 353(e)(2)(A), to wit: the defendant caused the wholesale distribution through Taranis Medical Corp. of the prescription drugs and other prescription drugs at a time when Taranis Medical Corp. was not licensed as a “Prescription Drug Wholesaler” in New York or any other state, contrary to Title 21, United States Code, Section 331(t) and 333(b)(1)(D).

The statutes defendant is charged with violating are sections 353(e), 331(t), and 333(b)(1)(D) of Title 21 of the United States Code. Section 353 (e) provides, in relevant part:

(e) Wholesale distributors; guidelines for licensing . . . No person may engage in wholesale distribution of a drug subject to subsection (b)(1) in any State unless such person -- (i)(I) is licensed by the State from which the drug is distributed.

Section 331(t) provides, in relevant part:

The following acts and the causing thereof are prohibited: (t) The importation of a drug in violation of section 381(d)(1) of this title . . . the distribution of drugs in violation of section 353(e) of this title . . .

Section 333(b)(1)(D) provides, in relevant part:

(b) Prescription drug marketing violations -- (1) Notwithstanding subsection (a) of this section, any person who violates section 331(t) of this title by -- (D) knowingly distributing drugs in violation of section 353(e)(1) of this title,

In order for the defendant to be found guilty of that charge, the government must prove beyond a reasonable doubt that the defendant knowingly distributed “prescription drugs,” as that term was previously defined in these instructions, in interstate commerce to someone other than a consumer or patient without being licensed to do so by the State of New York.

Authority: 21 U.S.C. § 353(e); United States v. Milstein, 401 F.3d 53 (2d Cir. 2005).

REQUEST NO. 32

Aiding and Abetting

For Counts 2-18, 20-36, 38-54, 55-71, 72-75, you may find defendant guilty of the offenses charged if you find beyond a reasonable doubt that the government has proven that another person actually committed the offenses with which defendant is charged and that defendant caused and/or aided or abetted that person in the commission of the offenses.

The aiding and abetting statute, Section 2 of Title 18 of the United States Code, provides:

- 1) whoever commits an offense against the United States or aids, abets, counsels, commands, induces or procures its commission, is punishable as a principal;
- 2) whoever willfully causes an act to be done which if directly performed by him or another would be an offense against the United States, is punishable as a principal.

Under this statute, it is not necessary for the government to show that the defendant himself committed the crime with which he is charged in order for you to find the defendant guilty. This is because a person who aids or abets another to commit a crime is just as guilty of that offense as if he committed it himself.

Accordingly, you may find a defendant guilty of any of the crimes charged in Counts 2-18, 20-36, 38-54, 55-71 and 72-75 of the indictment if you find beyond a reasonable doubt that the government has proved that another person actually committed the offense with which the defendant is charged, and that the defendant aided or abetted that person in the commission of the crime. The government must first prove that another person has actually committed the crime charged. No one can be convicted of aiding and abetting criminal acts of another if no crime was committed by the other person.

If you do find that a crime was committed, then consider whether the defendant aided or abetted the commission of the crime. To aid or abet, it is necessary that the defendant knowingly associated himself in some way with the crime and that he participated in the crime by doing some act to help make the crime succeed, intending to participate and make it succeed.

The mere presence of the defendant where a crime is being committed, even coupled with knowledge by the defendant that a crime is being committed, or the mere acquiescence by a defendant in the criminal conduct of others, even with guilty knowledge, is not sufficient to establish aiding and abetting. An aider and abettor must have some interest in the criminal venture.

To determine whether the defendant aided or abetted the commission of the crime with which he is charged, ask yourself these questions:

- 1) Did he participate in the crime charged as something he wished to bring about?
- 2) Did he knowingly associate himself with the criminal venture?
- 3) Did he seek by his actions to make the criminal venture succeed?

If he did all these things, then the defendant is an aider and abettor, and therefore guilty of the offense. If, on the other hand, your answer to any of these questions is “no,” then the defendant is not an aider and abettor, and you must find him not guilty.

Authority: Adapted from Sand, Instructions §§ 11-1 and 11-2; Hon. Carol B. Amon, United States v. Mazella, 11-300 (CBA); Hon. Jack B. Weinstein, United States v. Burks, 08-332 (JBW).

REQUEST NO. 33

Advice of Counsel

There are three elements to the affirmative defense of advice of counsel. First, a party seeking to avail himself of the defense must show that he honestly and in good faith sought the advice of counsel. Second, the party must establish that he fully and honestly put forth all the facts before his counsel. Last, the party must show that he followed counsel's advice in good faith and honestly, believing it to be correct and intending that his acts be lawful.

The defense is inapplicable when a party cannot satisfy all three elements. Thus, even if the defendant can show some elements, the defense must be precluded if even one element cannot be satisfied.

Authority: United States v. Colasuonno, 697 F. 3d 164, 181 (2d Cir. 2012) (quoting Williamson v. United States, 207 U.S. 425, 453 (1908)); United States v. Beech-Nut Nutrition Corp., 871 F.2d 1181, 1194-95 (2d Cir. 1989).

REQUEST NO. 34

Acts and Statements of Others

You will recall that I have admitted into evidence against the defendant the acts and statements of others because these acts and statements were committed by persons who, the government charges were also confederates or co-conspirators of the defendant on trial.

The reason for allowing this evidence to be received against the defendant has to do with the nature of the crime of conspiracy. A conspiracy is often referred to as a partnership in crime. Thus, as in other types of partnerships, when people enter into a conspiracy to accomplish an unlawful end, each and every member becomes an agent for the other conspirators in carrying out the conspiracy.

Accordingly, the reasonably foreseeable acts, declarations, statements and omissions of any member of the conspiracy and in furtherance of the common purpose of the conspiracy, are deemed, under the law, to be the acts of all of the members, and all of the members are responsible for such acts, declarations, statements and omissions.

If you find, beyond a reasonable doubt, that the defendant was a member of the conspiracy charged in the indictment, then, any acts done or statements made in furtherance of the conspiracy by persons also found by you to have been members of that conspiracy, may be considered against that defendant. This is so even if such acts were done and statements were made in the defendant's absence and without his knowledge.

However, before you may consider the statements or acts of a co-conspirator in deciding the issue of the defendant's guilt, you must first determine that the acts and statements were made during the existence, and in furtherance, of the unlawful scheme. If the acts were done or the statements made by someone whom you do not find to have been a member of the conspiracy

or if they were not done or said in furtherance of the conspiracy, they may be considered by you as evidence only against the member who did or said them.

Authority: Sand, Modern Federal Jury Instructions, § 19-9.

REQUEST NO. 35

No Duty to Call All Witnesses to an Event

There are several persons whose names you have heard during the course of the trial but who did not appear here to testify. I instruct you that each party had an equal opportunity or lack of opportunity to call any of these witnesses. Therefore, you should not draw any inferences or reach any conclusions as to what they would have testified to had they been called. Their absence should not affect your judgment in any way.

You also should, however, remember my instruction that the law does not impose on a defendant in a criminal case the burden or duty of calling any witness or producing any evidence.

Authority: Adapted from Sand et al., Modern Federal Jury Instructions, Instruction No. 6-7; see also United States v. Bahna, 68 F.3d 19, 22 (2d Cir. 1995).

REQUEST NO. 36

Interviews of Witnesses

There was testimony at trial that attorneys for the government and for the defense interviewed witnesses while preparing for and during the course of the trial. You should not draw any unfavorable inference from that fact. To the contrary, the attorneys were obliged to prepare their case as thoroughly as possible and, in the discharge of that responsibility, properly interview witnesses before trial and as necessary throughout the course of the trial.

Authority: Adapted from Hon. Carol B. Amon, United States v. Mazella, 11-300 (CBA); Hon. John Gleeson, United States v. Mendoza, et al., 09-292 (JG).

REQUEST NO. 37

Prior Inconsistent Statement

You have heard evidence that a witness made a statement on an earlier occasion which counsel argues is inconsistent with the witness's trial testimony. Evidence of a prior inconsistent statement is not to be considered by you as affirmative evidence bearing on the defendant's guilt. Evidence of the prior inconsistent statement was placed before you for the limited purpose of helping you decide whether to believe the trial testimony of the witness. If you find that the witness made an earlier statement that conflicts with his or her trial testimony, you may consider that fact in deciding how much of the witness's trial testimony, if any, to believe.

In making this determination, you may consider whether the witness purposely made a false statement or whether it was an innocent mistake; whether the inconsistency concerns an important fact, or whether it had to do with a small detail; whether the witness had an explanation for the inconsistency, and whether that explanation appealed to your common sense. It is exclusively your duty, based upon all the evidence and your own good judgment, to determine whether the prior statement was inconsistent, and if so, how much, if any, weight to be given to the inconsistent statement in determining whether to believe all or part of the witness's testimony.

Authority: Adapted from Sand, Instruction 7-19; Hon. Kiyo A. Matsumoto, United States v. Shabani Khamisi Jabu, 12-CR-454 (KAM).

REQUEST NO. 38

Testimony Pursuant to Cooperation and Non-Prosecution Agreements

In this case, there has been testimony from government witnesses who pled guilty after entering into an agreement with the government to testify. There is evidence that the government agreed to bring the witnesses' cooperation to the attention of the sentencing court in exchange for the witnesses' agreement to plead guilty and testify at this trial, or to cooperate in other investigations.

The government is permitted to enter into these kinds of plea agreements, which are called cooperation agreements. You, in turn, may accept the testimony of such a witness and convict the defendant on the basis of this testimony alone, if it convinces you of the defendant's guilt beyond a reasonable doubt.

However, you should bear in mind that a witness who has entered into such an agreement has an interest in this case different than any ordinary witness. You may conclude that a witness who realizes that he may be able to receive a lighter sentence by giving testimony favorable to the prosecution, has a motive to testify falsely. Therefore, you must examine such a witness's testimony with caution and weigh it with great care. If, after scrutinizing his or her testimony, you decide to accept it, you may give it whatever weight, if any, you find it deserves.

There has also been testimony from witnesses who have testified under an Order of Immunity from the Court. They cannot be prosecuted for any crimes which they may have admitted either here in court or in interviews with the prosecutors. The government is similarly entitled to make these kinds of promises, called immunity agreements and entitled to call as witnesses people to whom these promises are given. And, as with cooperating witnesses who have pled guilty to crimes, you may accept the testimony of a witness subject to an immunity

agreement and convict the defendant on the basis of this testimony alone, if the testimony convinces you of the defendant's guilt beyond a reasonable doubt. However, you should remember that a witness who has entered into a non-prosecution agreement has a different interest than a regular witness. A witness who realizes that he may be able to avoid prosecution by giving testimony favorable to the prosecution may also have a motive to testify falsely. Therefore you must also scrutinize this testimony with caution and weigh it carefully.

Authority: Adapted from Sand, Instruction 7-11; United States v. Tsirlina, 13-305 (RJD)(E.D.N.Y); United States v. Mahamadou Daff, 13-150 (NRB) (S.D.N.Y.).

REQUEST NO. 39

Government Employee Witnesses

During the trial, you have heard testimony from law enforcement agents. The mere fact that a witness is employed by the federal government as a law enforcement agent does not mean that his or her testimony is deserving of more or less consideration or greater or lesser weight than that of an ordinary witness. It is for you to decide, after weighing all the evidence and in light of the instructions I have given you about the factors relevant to determining the credibility of any witness, whether to accept the testimony of a law enforcement witness, and what weight, if any, that testimony deserves.

Authority: Adapted from Sand, Instruction 7-16; Hon. Carol B. Amon, United States v. Mazella, 11-300 (CBA); Hon. John Gleeson, United States v. Mendoza, et al., 09-292 (JG).

REQUEST NO. 40

Punishment

The question of possible punishment of the defendant, should that become necessary, is of no concern to the jury and it should not, in any sense, enter into or influence your deliberations. The duty of imposing a sentence, should that become necessary, rests exclusively with me, the Court. Your function is to weigh the evidence in the case, and to determine whether or not the defendant is guilty beyond a reasonable doubt, solely upon the basis of the evidence. Under your oath as jurors, you cannot allow a consideration of the punishment that may be imposed upon a defendant, if he is convicted, to influence your verdict, in any way, or, in any sense, to enter into your deliberations.

Authority: Adapted from Sand et al., Modern Federal Jury Instructions, Instruction 9-1; Hon. Carol B. Amon, United States v. Mazella, 11-300 (CBA); Hon. John Gleeson, United States v. Mendoza, et al., 09-292 (JG).

CONCLUSION

The government respectfully requests that the Court include the foregoing in its instructions to the jury. In addition, the government requests the opportunity to submit further instructions or amend those submitted as appropriate.

Dated: Central Islip, New York
November 4, 2015

Respectfully submitted,

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